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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,484	07/25/2003	Harry Kochat	X-0225	4225
75	90 08/25/2004		EXAM	INER
Thomas J. Dodd BioNumerik Pharmaceuticals, Inc. Suite 1250			OH, TAYLOR V	
			ART UNIT	PAPER NUMBER
8122 Datapoint Drive San Antonio, TX 78229			1625	
		DATE MAILED: 08/25/2004		

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)			
	10/627,484				
Office Action Summary	Examiner	KOCHAT ET AL.			
		Art Unit			
The MAILING DATE of this communication and	Taylor Victor Oh	1625			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
1) Responsive to communication(s) filed on <u>25 July 2003</u> .					
2a) This action is FINAL . 2b) This action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims					
 4) Claim(s) 1-7 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 1-7 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. 					
Application Papers 9)☐ The specification is objected to by the Examiner.					
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).					
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
Priority under 35 U.S.C. § 119					
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 					
Attachment(s)					
1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)					
Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date	Paper No(s)/Mail I	Patent Application (PTO-152)			

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The Status of Claims:

Claims 1-7 are pending.

Claims 1-7 have been rejected.

DETAILED ACTION

1. Claims 1-7 are under consideration in this Office Action.

Priority

2. It is noted that the application claims a benefit of 60/421,489 (10/25/02).

Drawings

3. None.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the terms, "substantially", "analogs", and "derivative" are recited. They are vague and indefinite. The expression of those terms are

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without further clarification by the specification. Therefore, an appropriate correction is required.

In claims 4 and 5, the phrases "the 4-enamine <u>derivative</u>" and "the 4-hydroxymethylidene <u>derivative</u>" are recited. They are vague and indefinite. The expression of those phrases are without further clarification by the specification. Therefore, an appropriate correction is required.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Ezquerra et al(Tetrahedron: Asymmetry (1994), 5(5), p. 921-6) discloses the process of preparing 4-methylene-L-glutamic acid in the following steps:

- a. reacting a solution of (Me₃Si)₂NH in dry THF and a solution of ethyl N-Boc-pyroglutamate at –78 °C and allowing the reaction mixture at room temperature, and further hydrolyzing the resultant solution with water;
- b. reducing ethyl-1-(tert-butoxycarbonyl)-4(dimethylaminomethyl)pyroglutamate in the presence of NaHCO₃ at room temperature;
- c. hydrolyzing ethyl-1-(tert-butoxycarbonyl)-4(methylene)pyroglutamate in the presence of lithium hydroxide in
 THF followed by treatment of HCI in ETOAC at room
 temperature.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*** Jay 8/27/54

for Lecilia Tsang.